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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/443,986	11/19/1999	DANIEL JOSEPH OMAHONY	99.1064.US	8043

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EXAMINER	
ROBINSON, HOPE A	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/443,986	OMAHONY, DANIEL JOSEPH	
	Examin r	Art Unit	
	Hope A. Robinson	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-26,28,29,35-39,44-88 and 114-138* is/are pending in the application.

4a) Of the above claim(s) *18-26,28,29,35-39 and 44-113* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *114-138* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11/19/99* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's response to the Office Action mailed April 29, 2004 on October 6, 2004, is acknowledged.

2. It is noted that applicant submitted new claims 89-113 in an amendment filed March 8, 2004 and the amendment was non-compliant. Applicant re-submitted the claims in an amendment on June 4, 2004 however, the claims were not renumbered. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (**whether entered or not**).

Misnumbered claims 89-113 have been renumbered 114-138.

Claim Disposition

3. Claims 1-17, 27, 30-34 and 40-43 have been cancelled. Claims 18-26, 28-29, 35-39, 44-138 are pending. Claims 18-26, 28-29, 35-39 and 44-113 stand withdrawn from consideration as drawn to a nonelected invention. Claims 114-138 are under examination.

Specification

4. The specification is objected to because of the following informalities:

The specification is objected to because the priority information is not listed on page 1, for example: "This application claims priority to U.S. Provisional Application No. 60/109,038 filed on November 19, 1998.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 114, 115-125 and 127-138 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is directed to a retro-inverted peptide comprising residues that specifically binds to a gastro-intestinal tract receptor. The claims are also directed to a composition comprising said peptide that is bound to an active agent, said active agent being of value in the treatment of a mammalian disease or disorder. The instant claims do not recite the specific disease or disorder and the specification does not demonstrate the claimed composition in a medicament to treat any disease or disorder.

There is no indication of what "value" the active agent has in the treatment of any or all the mammalian diseases encompassed in the claims. Furthermore, what the retro-inverted peptide binds to does not define the structure or properties of the peptide *per se*. Note that the claimed invention is only defined by function not by a structure. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. See *Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir.1997)*. Therefore, a biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. For example, even though a genetic code table would correlate a known amino acid sequence with a genus of coding nucleic acids, the same table cannot predict the native, naturally occurring nucleic acid sequence of a naturally occurring mRNA or its corresponding cDNA. *See MPEP 2163.*

Further, *Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir.1991)*, states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in *possession of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-*

Cath at page 1116). The skilled artisan cannot envision the detailed chemical structure of the encompassed genus of encoded proteins, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. *See Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993). See MPEP 2163.*

Therefore, for all these reasons the specification lacks adequate written description, and one of skill in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

6. Claims are 114-138 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the retro-inverted peptide and the specific sequences (SEQ ID NOS: 1-3), does not reasonably provide enablement for fragments of the claimed peptides or a composition for treatment of any mammalian disease or disorder. The enablement requirement refers to the requirement that the specification describe how to make and how to use the invention. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to:

I. Quantity of Experimentation Necessary:

The claimed invention is directed to a retro-inverted peptide and fragments of the claimed peptide (see for example claims 114 and 117-120), however, the claims do not include a structure. Note that the claims are only defined by a function. Claim 114 for example, is directed to a peptide that specifically binds to a gastro-intestinal tract receptor, however, the use of the term "specifically" is relative as no disassociation constant is provided in the claim to exemplify the binding specificity. Further, there is no nexus between the peptide of claim 114 and the peptide of claim 116 as both peptides lack a structure and are defined by separate and distinct activities. In addition, claims such as 117-120 recite "wherein the peptide comprises no more than 50 amino acid residues; no more than 40 amino acid residues; no more than 30 amino acid residues and no more than 20 amino acid residues and there is no indication that these fragments will retain the activity recited in claims 114 or 116. Moreover, the claims are directed to a composition, said composition comprises the peptide and is bound to a material comprising an active agent, said active agent being of value in the treatment of a mammalian disease or disorder. It is noted that claims 115 and 126 recite a structure, however, the claims do not remedy the deficiencies of the claimed composition.

The claims do not recite the specific disease or disorder and the specification does not demonstrate the claimed composition in a medicament to treat any disease or disorder. Further, there is no indicia as to how to ascribe value to the active agent which is simply defined as a drug. Moreover, neither the claims nor the specification provides any showing of the claimed fragments in association with the claimed

invention. Page 5 of the specification provides a discussion as to what is considered to be a derivative. However, there is no showing of any biological activity for the claimed derivative, no sequence identifiers or any special characteristics described. Moreover, the specification provides no description of the claimed fragment or any special features to enable one skilled in the art to be able to practice the full scope of the claimed invention. Therefore, the present application lacks sufficient guidance as to the claimed invention. Further, the specification does not provide any exemplification of the claimed invention with the unspecified amount of fragments or a medicament to treat any or all diseases/disorders. Therefore, the claimed invention does not enable one skilled in the art to be able to make and use the invention without undue experimentation.

II. Amount of direction or guidance presented:

The specification does not provide adequate guidance to be able to practice the claimed invention commensurate in scope with the claims. To examine every fragment to determine function/biological activity would require undue experimentation. In addition, there is no indicia as to the binding specificity to the receptors and if the peptide fragments will retain the binding activity. Furthermore, no guidance is provided as to what disease or disorder the peptide/fragments will be used to treat or what value is to be placed to obtain a peptide that results in treatment of a mammalian disease/disorder.

III. Presence or absence of working examples:

No working examples are provided *per se*. The specification discusses an animal study involving the bioavailability of insulin. It is difficult to ascertain the nature of the claimed invention from this one record and there is no demonstration of the claimed composition in a therapy or the peptide fragments.

IV. Nature of the Invention:

The nature of the invention is a retro-inverted peptide or fragment that specifically binds to gastro-intestinal tract receptor (see for example claim 114). However, the specification does not provide sufficient guidance/direction to enable the full scope of the claimed invention as the claimed derivative/fragment is not described by size, length or function.

V. State of the prior art and Relative skill of those in the art:

It is disclosed in the specification on page 3 that the applicants have found retro-inverted forms of the GIT targeting agents specific receptor sites in vivo and/or promote uptake of active agents and/or enhance active agent delivery across the GIT into the systemic circulation. The claims are directed to fragments of the peptides and no characteristics or attributes of these have been described. As the prior art is silent on the claimed sequences a high level of skill was required at the time the application was filed.

VI. Predictability or unpredictability of the art:

Since very little is known in the prior art about the nature of the invention renders the art unpredictable. The specification should then give more details as to how to make and use the invention in order to be enabling.

VII. Breadth of the claims:

The breadth of the claims are very broad and encompass any disease/disorder and any fragment of the claimed sequences. The specification does not provide support for the broad scope of the claims, which encompass an unspecified amount of fragments and a plurality of diseases/disorders. The issue in this case is the breath of the claims in light of the predictability of the art as determined by the number of working examples, the skill level artisan and the guidance presented in the instant specification and the prior art of record. This make and test position is inconsistent with the decisions of *In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970)* where it is stated that "...scope of claims must bear a reasonable correlation to scope of enablement provided by the specification to persons of ordinary skill in the art...". Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See *In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988)*. Thus, for all these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention.

7. Applicant's remarks made in the amendments filed on October 6, 2004, March 8, 2004 and June 4, 2004 are noted. However, the above grounds of rejections have been instituted for the reasons stated above.

Conclusion

8. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday from 9:00 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS-~~AP~~

Patent Examiner 12/29/04

JON WEBER
SUPERVISORY PATENT EXAMINER